

## Orbifloxacin Liquid Formulation

Version 4.0      Revision Date: 30.09.2023      SDS Number: 785872-00016      Date of last issue: 04.04.2023  
Date of first issue: 28.06.2016

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Eye)

##### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.

# SAFETY DATA SHEET

according to the Globally Harmonized System



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P260 Do not breathe mist or vapours.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P318 IF exposed or concerned, get medical advice.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name    | CAS-No.     | Concentration (% w/w) |
|------------------|-------------|-----------------------|
| Orbifloxacin     | 113617-63-3 | >= 3 - < 5            |
| Silicon dioxide  | 7631-86-9   | >= 1 - < 5            |
| Lactic acid      | 50-21-5     | >= 1 - < 3            |
| Sodium hydroxide | 1310-73-2   | >= 1 - < 2            |

### 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### 7. HANDLING AND STORAGE

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- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components       | CAS-No.     | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------------|-------------|-------------------------------|--|----------|
| Orbifloxacin     | 113617-63-3 | TWA                           | 0.2 mg/m <sup>3</sup> (OEB 2)                  | Internal |
| Silicon dioxide  | 7631-86-9   | TWA (Total dust)              | 10 mg/m <sup>3</sup> (Silica)                  | IN OEL   |
| Sodium hydroxide | 1310-73-2   | CEIL                          | 2 mg/m <sup>3</sup>                            | IN OEL   |
|                  |             | C                             | 2 mg/m <sup>3</sup>                            | ACGIH    |

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

#### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type
- Hand protection : Chemical-resistant gloves
- Material
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

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Skin and body protection : aerosols.  
: Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : light brown

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

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Partition coefficient: n-octanol/water : No data available  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity  
  Viscosity, kinematic : No data available  
Explosive properties : Not explosive  
  
Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : No data available  
Particle size : No data available

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method  
  
Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### **Components:**

##### **Orbifloxacin:**

|| Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg

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|   |  |
|---|--|
|   | Remarks: No mortality observed at this dose.   |
|   | LD50 (Mouse): > 2,000 mg/kg<br>Remarks: No mortality observed at this dose.  |
|   | LD50 (Dog): > 600 mg/kg<br>Symptoms: Vomiting<br>Remarks: No mortality observed at this dose.  |
| Acute inhalation toxicity                       | : Remarks: No data available   |
| Acute dermal toxicity                           | : Remarks: No data available   |
| Acute toxicity (other routes of administration) | : LD50 (Rat): > 200 mg/kg<br>Application Route: Intramuscular<br><br>LD50 (Mouse): 500 mg/kg<br>Application Route: Intramuscular<br><br>LD50 (Rat): 233 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 250 mg/kg<br>Application Route: Intravenous |
| <b>Silicon dioxide:</b>                         |  |
| Acute oral toxicity                             | : LD50 (Rat): > 5,000 mg/kg<br>Method: OECD Test Guideline 401   |
| Acute inhalation toxicity                       | : LC50 (Rat): > 2.08 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity   |
| Acute dermal toxicity                           | : LD50 (Rabbit): > 5,000 mg/kg   |
| <b>Lactic acid:</b>                             |  |
| Acute oral toxicity                             | : LD50 (Rat): > 2,000 mg/kg<br>Remarks: Based on data from similar materials   |
| Acute inhalation toxicity                       | : LC50 (Rat): > 5 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>Assessment: Corrosive to the respiratory tract.<br>Remarks: Based on data from similar materials  |
| Acute dermal toxicity                           | : LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity<br>Remarks: Based on data from similar materials   |

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### **Sodium hydroxide:**

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

### **Skin corrosion/irritation**

Not classified based on available information.

### **Product:**

Species : Rabbit  
Result : No skin irritation

### **Components:**

#### **Orbifloxacin:**

Species : Rabbit  
Method : Draize Test  
Result : No skin irritation

#### **Silicon dioxide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### **Lactic acid:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Corrosive after 1 to 4 hours of exposure  
Remarks : Based on data from similar materials

### **Sodium hydroxide:**

Result : Corrosive after 3 minutes or less of exposure

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Product:**

Species : Rabbit  
Result : Mild eye irritation

### **Components:**

#### **Orbifloxacin:**

Species : Rabbit  
Method : Draize Test  
Result : Mild eye irritation

#### **Silicon dioxide:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation



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### Lactic acid:

Species : Chicken eye  
Remarks : Based on data from similar materials

Result : Irreversible effects on the eye

### Sodium hydroxide:

Result : Irreversible effects on the eye  
Remarks : Based on skin corrosivity.

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Product:

Test Type : Magnusson-Kligman-Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : Not a skin sensitizer.

### Components:

#### Orbifloxacin:

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : Not a skin sensitizer.

#### Lactic acid:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

#### Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)  
Exposure routes : Skin contact  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

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### Components:

#### **Orbifloxacin:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: equivocal
- Test Type: Mouse Lymphoma  
Result: positive
- Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: positive
- Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Intraperitoneal injection  
Result: negative
- Test Type: unscheduled DNA synthesis assay  
Species: Rat  
Cell type: Liver cells  
Application Route: Oral  
Result: negative
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

#### **Silicon dioxide:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative
- Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Lactic acid:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

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Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Orbifloxacin:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 200 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 200 mg/kg body weight  
Result : negative

#### **Silicon dioxide:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 103 weeks  
Result : negative

#### **Lactic acid:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

### **Reproductive toxicity**

Suspected of damaging the unborn child.

### **Components:**

#### **Orbifloxacin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 50 mg/kg body weight  
Early Embryonic Development: NOAEL: 50 mg/kg body weight  
Result: No adverse effects

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight

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Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 20 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight  
Result: No effects on early embryonic development, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain

Test Type: Development  
Species: Dog  
Application Route: Oral  
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight  
Result: Effects on postnatal development, Skeletal malformations

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### **Silicon dioxide:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **Lactic acid:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

### **Product:**

Target Organs : Eye  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### **Product:**

Species : Dog  
NOAEL : 22.5 mg/kg

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LOAEL : 37.5 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Symptoms : Gastrointestinal disturbance

Species : Dog  
LOAEL : 75 mg/kg  
Application Route : Oral  
Exposure time : 10 Days  
Symptoms : Salivation, Gastrointestinal disturbance, Vomiting

Species : Cat  
LOAEL : 45 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Target Organs : Eye  
Symptoms : Salivation, Lachrymation, Gastrointestinal disturbance, Liver disorders

### Components:

#### **Orbifloxacin:**

Species : Rat  
NOAEL : 20 mg/kg  
LOAEL : 80 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Testis, Liver, Kidney, spleen

Species : Mouse  
NOAEL : 80 mg/kg  
LOAEL : 250 mg/kg  
Application Route : Oral  
Exposure time : 3 Months

Species : Juvenile dog  
NOAEL : 50 mg/kg  
LOAEL : 250 mg/kg  
Application Route : Oral  
Exposure time : 14 Days  
Target Organs : Heart, Bone  
Symptoms : Gastrointestinal disturbance  
Remarks : mortality observed

Species : Juvenile dog  
NOAEL : 2 mg/kg  
LOAEL : 3 mg/kg  
Application Route : Oral  
Exposure time : 90 Days  
Target Organs : Bone  
Remarks : No significant adverse effects were reported

Species : Dog  
NOAEL : 37.5 mg/kg

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Application Route : Oral  
Exposure time : 30 Days

Species : Cat  
NOAEL : 7.5 mg/kg  
LOAEL : 22.5 mg/kg  
Application Route : Oral  
Exposure time : 1 Months  
Symptoms : Gastrointestinal disturbance

### Silicon dioxide:

Species : Rat  
NOAEL : 1.3 mg/m3  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

### Lactic acid:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks  
Remarks : Based on data from similar materials

Species : Rat  
LOAEL : 886 mg/kg  
Application Route : Skin contact  
Exposure time : 13 Weeks

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Orbifloxacin:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash  
Remarks: May cause photosensitisation.

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Silicon dioxide:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

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aquatic invertebrates      Exposure time: 24 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants      :    EC50 ( Desmodesmus subspicatus (green algae)): > 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

NOEC ( Desmodesmus subspicatus (green algae)): 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

### Lactic acid:

Toxicity to fish      :    LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates      :    EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants      :    ErC50 ( Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

NOEC ( Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms      :    EC50: > 10 - 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

#### Lactic acid:

Biodegradability      :    Result: Not readily biodegradable.  
Remarks: Based on data from similar materials

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### Bioaccumulative potential

#### Components:

##### Lactic acid:

Partition coefficient: n-octanol/water : log Pow: -0.62

##### Mobility in soil

No data available

##### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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### 16. OTHER INFORMATION

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#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / C : Ceiling limit  
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)  
IN OEL / CEIL : ceiling limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Orbifloxacin Liquid Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.0     | 30.09.2023     | 785872-00016 | Date of first issue: 28.06.2016 |

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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